REMARKS

Claims 1, 6-10 and 12 are pending in the subject application. Applicants have hereinabove amended claim 1 and added new claims 50-56. Support for these amendments to the claims can be found, *inter alia*, in the specification as follows: claim 1: at page 22, lines 1-2 and 25-30; page 24, lines 25-27 and 34; and page 35, lines 1-3; claim 50: page 24, lines 25-27; claim 51: page 24, lines 27-31; claim 52: page 24, line 34; claim 53: page 24 line 24, to page 25, line 1; claim 54: page 25, lines 1-2; claim 55: page 25, line 2-3; claim 56: page 25, lines 2-3 Applicants maintain that no issue of new matter is raised by this amendment. Upon entry of the Amendment, claims 1 as amended, and claims 6-10, 12 and 50-56 will be pending and under examination.

Rejection under 35 U.S.C. §102(b)

The Examiner rejected claims 1, 6, 8-10 and 12 under 35 U.S.C. §102(b) as allegedly anticipated by Riley, et al. (Environmental Toxicology and Pharmacology, 7:109-118 (1999)) for the reason of record as set forth in the June 5, 2007 Office Action at page 4-5. The Examiner alleged that applicants remarks in the September 5, 2007 Amendment In Response to June 5, 2007 Office Action that Riley et al. do not teach the instant agent that specifically inhibits *de novo* synthesis of ceramide in human cells but instead uses animal cells, such as mice, was not persuasive. The Examiner further alleged that since animal cells or animal models are routinely used to perform experiments and are equivalent to human cell experiments that inherently, the experimental data results from animal models are sufficient enough for human cell results.

In response, applicants respectfully traverse the Examiner's ground of rejection. Nevertheless, without conceding the correctness of the Examiner's rejection, applicants note that claim 1 has been amended hereinabove. Applicants, however, will address the Examiner's

comments in relation to amended claim 1 and the claims dependent thereof.

Applicants' invention, as recited in amended claim 1, provides a method for decreasing the amount of mature sterol regulatory element binding proteins and cholesterol synthesis in a human cell of a subject having a disorder characterized by an elevated level of mature sterol regulatory element binding proteins and elevated cholesterol synthesis comprising contacting the human cell with an agent that specifically inhibits *de novo* synthesis of ceramide in the cell, so as to thereby decrease the amount of mature sterol regulatory element binding proteins and cholesterol synthesis in the human cell, wherein the human cell is a hepatocyte or an adipocyte and the disorder is a lipid disorder or Hereditary Sensory Neuropathy, Niemann Pick Disease Type A and Niemann Pick Disease Type B.

Riley et al. disclose administration of myricocin to pig epithelial cells and administration of myriocin to Balb/C mice. Nowhere do Riley et al. disclose administration of myriocin to a human cell and Riley et al. certainly do not disclose administration of myriocin to a human cell that is an adipocyte or a hepatocyte. In addition, Balb/c mice are not suffering from a disorder that is characterized by an elevated level of mature sterol regulatory element binding proteins and elevated cholesterol synthesis. Riley et al., therefore, do not recite each and every element of applicants' invention, as recited in amended claim 1.

In view of these remarks, applicants maintain that as amended, claim 1, and the claims dependent thereof, are not anticipated by Riley et al. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

Rejection under 35 U.S.C. 103(a)

The Examiner further rejected claims 1, 6-10 and 12 under 35 U.S.C. §103(a) as allegedly obvious by Riley, et al.

In support of the obviousness rejection, the Examiner reiterated the remarks made in support of the rejection under 35 U.S.C. §102(b). The Examiner indicated that applicants have not demonstrated on the record a side-by-side comparison of the results from the prior art versus the present invention. Notwithstanding the foregoing, the Examiner acknowledged on pages 3 and 4 of the Office Action that "The results from the present invention produce unexpected results over the animal models producing the same desired mechanism." (Emphasis added).

In response, applicants respectfully traverse the Examiner's ground of rejection. Nevertheless, without conceding the correctness of the Examiner's rejection, applicants note that claim 1 has been amended hereinabove. Applicants, however, will address the Examiner's comments in relation to amended claim 1 and the claims dependent thereof.

As an initial matter, applicants note that it is not clear why the Examiner is rejecting the claims if the Examiner is acknowledging, as noted above, that "The results from the present invention produce unexpected results over the animal models producing the same desired mechanism". Unexpected results would render applicants invention non-obvious over Riley et al.

Riley et al. disclose administration of myricocin to pig epithelial cells and administration of myriocin to Balb/C mice to reverse the harmful effects of fumonisin. Nowhere do Riley et al. disclose administration of myriocin to a human cell and Riley et al. certainly do not disclose administration of myriocin to a human cell that is an adipocyte or a hepatocyte. In addition, Balb/c mice are not suffering from a disorder that is characterized by an elevated level of mature sterol regulatory element binding proteins and elevated cholesterol synthesis. Riley et al. do not disclose a subject suffering from such a disorder.

In contrast, applicants' invention, as recited in amended claim 1, provides a method for decreasing the amount of mature sterol

regulatory element binding proteins and cholesterol synthesis in a human cell of a subject having a disorder characterized by an elevated level of mature sterol regulatory element binding proteins and elevated cholesterol synthesis comprising contacting the human cell with an agent that specifically inhibits *de novo* synthesis of ceramide in the cell, so as to thereby decrease the amount of mature sterol regulatory element binding proteins and cholesterol synthesis in the human cell, wherein the human cell is a hepatocyte or an adipocyte and the disorder is a lipid disorder or Hereditary Sensory Neuropathy, Niemann Pick Disease Type A and Niemann Pick Disease Type B.

Applicants maintain that it would not be obvious from Riley et al., which only discloses administration of myriocin to pig epithelial cells and to Balb/c mice, to contact human adipocytes and human hepatocytes with myriocin, as recited in amended claim 1. In addition, no where do Riley et al. disclose administration of myriocin to a subject having a disorder that is characterized by an elevated level of mature sterol regulatory element binding proteins and elevated cholesterol synthesis. Accordingly, applicants maintain that it would not be obvious to a person having ordinary skill in the art, based on the disclosure of Riley et al., to arrive at applicants claimed invention, as recited in amended claim 1.

In view of these remarks, applicants maintain that claim 1, as amended, and the claims dependent thereof, are not rendered obvious by Riley et al. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

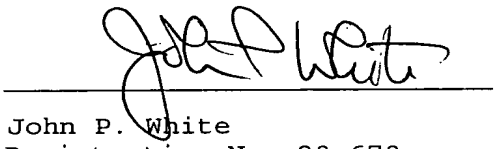
Summary

In view of the remarks hereinabove, applicants respectfully submit that the grounds of rejections set forth in the December 6, 2007 Final Office Action has been overcome. Applicants therefore respectfully Request that the Examiner reconsiders and withdraws the grounds of rejections and allow claims 1, as amended, and claims 6-10, 12 and 50-56.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fees, other than the $525.00 three-month extension fee and the $405.00 fee for filing a Request For Continued Examination (RCE), are deemed necessary in connection with the filing of this Amendment. Accordingly, a check in the amount of $930.00 is enclosed. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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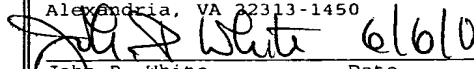

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